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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,541	03/01/2002	Benjamin R. Halpern	ABIOS.022A	2245
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Leonard D. Bowersox, Esquire KILYK & BOWERSOX, P.L.L.C. 3603-E Chain Bridge Road Fairfax, VA 22030				
		EXAMINER BORIN, MICHAEL L		
		ART UNIT 1631		
		MAIL DATE 06/18/2007		
		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/087,541

Applicant(s)

HALPERN, BENJAMIN R.

Examiner

Michael Borin

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1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/15/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 12-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Amendment filed 03/15/2007 is acknowledged.

Claims 20-7 are added. Claims 1-15, 17,19-27 are pending. Claims 1-7, 11, remain withdrawn from further consideration as being drawn to a non-elected groups.

Claim Rejections - 35 USC § 103.

Claims 8-10,12-27 are rejected under 35 U.S.C. 103(a) as unpatentable over Eriksson et al in view of Arnold et al. and further in view of Wilkins (J. Mol. Biol. 1999, 289,645-657).

The instant claims are drawn to method for comparing a modified query peptide to a plurality of database peptides. "Modified" means polypeptide modified by any post-translational modification, such as phosphorylation, oxidation, substitution, etc, which alters mass of the query polypeptide. The claimed method comprises the steps of: (a) identifying a fragmentation spectrum comprising a plurality of query mass values for query peptide; (b) dividing spectral range of the modified peptide into intervals, c) evaluating peptide fragments in each interval, and comparing fragments in each of said plurality of intervals with known fragments, scoring the fragments and identifying best matching fragments. A spectral range is the range from zero to the unmodified query

peptide's mass. The claims are now amended to add a step specifying that scores of the mass ratio comparison for each range of a query peptide fragment and known peptides is summed up before the identifying step.

Eriksson et al (US Patent 6,466,010) teaches method for assessing significance of protein identification. The method comprises steps of generating mass data for fragments of a query polypeptide (e.g., claim 1) wherein the polypeptide may have post-translational modifications (see col. 9, lines 42-44; claim 28) and compared to protein database, wherein the database comprises information on polypeptides which exhibit modifications. The query polypeptide is cleaved into a parts by a method that produces constituent parts in a predictable way (claim 42), and comparison can be constrained within a chosen mass range (claims 45, 47).

With regard to scoring, Eriksson teaches that mass comparison is scored with the score scores denoting a degree of similarity between data. A comparison is performed until sufficient quantity of scores is selected. See col. 8 and col. 12, first and second paragraph.

With regard to b-ions and y-ions (new claims 20-22, 24,25) In the process of collision-induced dissociation, a peptide bond at a random position is broken, and each molecule is fragmented into two *complementary* ions, typically an N-terminal ion called *b-ion* and a C-terminal ion called *y-ion*. Therefore, b- and y-ions are formed in the method of Eriksson.

Eriksson et al does not teach apportioning the spectral range into plurality of divisions.

Arnold et al teaches that matching of results of mass spectrometry with databases can be substantially improved by dividing spectral range into intervals. The reference teaches that dividing spectral range into intervals allows fine-tuning of correlation analysis and yields correlation indices that are more sensitive to spectral differences. See abstract, and p. 635. For example mass range from 3.5 to 10 kDa was divided into 13 intervals of 500 Da each before running comparative analysis. See p. 631, left column, bottom.

It would be *prima facie* obvious to one skilled in the art at the time the invention was made to be motivated to divide spectral range into plurality of divisions while using method of Eriksson et al because such subdivision into intervals was shown by Arnold to be beneficial for more precise detection and determination of spectral differences which is a desirable feature for spectral analysis of modified peptides in the method of Eriksson et al .

With regard to summing up the scores obtained from the intervals, as now addressed in the claims, Eriksson et al apparently would not teach such summing up because the method compares scores obtained for the entire molecule. Col. 8, lines 23-25. Therefore, as one would be motivated to divide spectral range into plurality of divisions while using method of Eriksson et al, as addressed above, and because Eriksson et al compares scores obtained for the entire molecule, one would be then motivated to sum up the scores obtained for intervals.

Further, with regard to the added limitation of excluding or adjusting modified mass ratios, the reference of Eriksson, although it does not teach excluding or adjusting modifications before comparative analysis, it addresses the issue of accounting for post-translational modifications. see col. 9, lines 39-61.

Wilkins teaches software FindMod which can identify post-translational modifications in residues of unknown peptides. Identifying such modifications thus allows to subtract their mass and compare thus corrected mass values of peptide with database data. Thus, for example, Wilkins describe a peptide of mass 1631 which did not match any database entry; however, after identifying potential modification and subtracting its value, the sequence of peptide was identified.

Therefore, It would be prima facie obvious to one skilled in the art at the time the invention was made to be motivated to apply approach of Wilkins in the scoring method of Eriksson to be able to match mass information of a query peptide and known database information because identification and removal of modified information allows more precise comparison with database information and thus enables identification of sequence of query protein which is the objective of mass-spectrum analysis.

Response to arguments

Applicant argues that neither Eriksson nor Arnold references address excluding or adjusting modified mass ratios. This newly added limitation is now addressed by adding reference of Williams et al.

Double Patenting

Claim 8-10,12-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/241751.

Applicant has indicated previously that filing Terminal Disclaimer will be considered upon identification of allowable subject matter in the instant application. In

turn, Examiner will revise the issue of double patenting upon identification of allowable subject matter in the instant application.

Conclusion.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb